EXHIBIT C

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.*	:	Civil A. No. _____
[UNDER SEAL]	:	
v.	:	FILED UNDER SEAL Pursuant to 31 U.S.C. § 3730(b)(2)
[UNDER SEAL]	:	JURY TRIAL DEMANDED

COMPLAINT

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES of AMERICA, and the STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, WISCONSIN, and the DISTRICT OF COLUMBIA, and the CITIES OF CHICAGO and NEW YORK, Plaintiffs, *ex rel.* RELATOR SCOTT CLARK, Relator, v. QUESTCOR PHARMACEUTICALS, INC. Defendant.	FILED *IN CAMERA* UNDER SEAL Pursuant to 31 U.S.C. § 3730(b)(2) Civil A. No. _____

COMPLAINT BROUGHT UNDER THE *QUI TAM* PROVISIONS OF THE FEDERAL FALSE CLAIMS ACT AND ANALOGOUS STATE AND LOCAL LAWS

I. NATURE OF THE ACTION

1. Relator Scott Clark ("Relator" or "Clark") brings this action on behalf of the United States of America, and State and Local Governments to recover damages and civil penalties for false claims presented by Defendant Questcor Pharmaceuticals, Inc. ("Defendant"

or "Questcor") to the United States ("United States"), the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin and the District of Columbia, and the Cities of Chicago and New York (collectively "State and City Plaintiffs").

2. This action arises under the provisions of Title 31 U.S.C. § 3729 *et seq*., known as the False Claims Act ("FCA"), and pursuant to analogous provisions of state and local law, including the following:

California False Claims Act, Cal. Gov't Code § 12651 *et seq*.
Colorado Medicaid False Claims Act, Rev. Stat. § 25.5-4-304 *et seq.*
Connecticut False Claims Act, Chapter 319v § 17b-301a *et seq.*
Delaware False Claims and Reporting Act, Del. Code Tit. 6, § 1201 *et seq.*
Florida False Claims Act, Fla. Stat. § 68-081 *et seq.*
Georgia False Medicaid Claims Act, Ga. Code § 49-4-168 (2007)
Hawaii False Claims Act - False Claims to the State, Haw. Rev. Stat. § 661-21 *et seq.*
Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/1 *et seq.*
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*
Iowa False Claims Act, Iowa Code Ann. § 685.1 *et seq.*
Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437.1 *et seq.*
Maryland False Claims Act, Md. Code Ann., Health-Gen. § 2-601 *et seq.*
Massachusetts False Claims Act, Mass Laws Ch. 12, § 5(A) *et seq.*
Michigan Medicaid False Claims Act, Mich. Comp Laws Serv. § 400.601 *et seq.*
Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*
Montana False Claims Act, Mont. Code § 17-8-401 *et seq.*
Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. § 357.010 *et seq.*
New Hampshire Medicaid False Claims Act, N.H. Rev. Stat. § 167:61-b *et seq.*
New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*
New Mexico Medicaid False Claims Act., N.M. Stat § 27-14-1 *et seq.*
New York False Claims Act, N.Y. St. Fin. Law § 187 *et seq.*
North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*
Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.*
Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*
Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq.*
Tennessee Medicaid False Claims Act, Tenn. Code § 71-5-181 *et seq.*
Texas Medicaid Fraud Prevention, Tex. Hum. Res. Code § 36.001 *et seq.*

Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq.*
Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. § 48.80.010 *et seq.*
Wisconsin False Claims Act, Wis. Stat. § 20.931 *et seq.*
District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.*
City of Chicago False Claims Act, Mun. Code, § 1-22-010 *et seq.*
New York City False Claims Act, Adm. Code § 7-801 *et seq.*

(collectively, "Analogous *Qui Tam* Statutes").

3. Under the above-cited statutes, this action seeks to recover treble damages and civil penalties on behalf of the United States and the State and City Plaintiffs, for false or fraudulent claims Defendant made, or caused to be made, for reimbursement from government health care programs for the off-label promotion and sales of H.P. Acthar® Gel ("Acthar"), a version of the hormone corticotropin.

4. Acthar stimulates the body to produce its own steroids, and Questcor charges more than $27,000 for a single vial. However, clinical studies have found that Acthar is no more effective than synthetic steroids, which are far less expensive.

5. Relator has extensive documentation and first-hand knowledge demonstrating that Defendant is promoting Acthar for unlawful, off-label uses, while providing illegal kickbacks to healthcare providers and patients for prescriptions.

6. Defendant submitted, or caused to be submitted, claims for reimbursement to federal and state government-funded programs including, without limitation, Medicaid, Medicare, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, and the Veterans Administration in violation of the FCA. The FCA specifically proscribes Defendant's conduct involving unlawful marketing and promotion of prescription drugs, illegal kickbacks, and the submission of false or non-reimbursable claims to Medicare, Medicaid and other government-funded health programs.

7. Defendant engaged in off-label and other illegal marketing activities in violation of the FCA and United States Food and Drug Administration ("FDA") laws and regulations.

8. The schemes also included improper inducements to healthcare providers and patients for prescriptions.

II. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction to this Court over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has subject matter jurisdiction over the counts relating to the State False Claims Acts pursuant to 31 U.S.C. § 3732(b), as well as supplemental jurisdiction over the counts relating to the State False Claims Acts pursuant to 28 U.S.C. § 1367.

10. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in this state and this judicial district. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one act proscribed by 31 U.S.C. § 3729 occurred in this district.

11. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)-(c) because Defendant Questcor transacts business within this District and because acts proscribed by 31 U.S.C. § 3729 occurred within this District.

12. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint is filed under seal and will remain under seal for a period of 60 days or more from its filing date or such other date as the Court so orders, and shall not be served upon the Defendant unless the Court so orders.

13. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any

other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730 (e)(4)(A), amended by Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010). However, Relator affirmatively disclosed the allegations herein to the United States Department of Justice prior to filing this action.

14. To the extent that there has been a public disclosure of the information upon which the allegations of this Complaint are based that is unknown to Relator, Relator is an "original source" of this information as defined in 31 U.S.C. § 3730(e)(4)(B), amended by Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010) and similar state law provisions. Relator possesses direct and independent knowledge of the information as a result of his employment with Defendant. Relator voluntarily provided the government with this information prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

III. THE PARTIES

15. Relator Scott Clark was hired by Defendant Questcor on September 16, 2010 to be an Acthar Specialist. He was assigned a territory that included all of Oregon and Vancouver, Washington.

16. Defendant Questcor is a corporation organized, existing, and doing business under the laws of the State of California. Questcor's corporate headquarters and principal place of business is in Anaheim, California.

17. Questcor Pharmaceuticals, Inc. is a biopharmaceutical company with essentially one product – Acthar, an injectable drug currently approved by the FDA for the treatment of a number of indications, including multiple sclerosis ("MS"), a condition of the central nervous system; nephrotic syndrome ("NS"), a kidney condition; and infantile spasms ("IS"), an epileptic condition affecting young children.

18. Upon information and belief, sales of Acthar account for more than 99% of Questcor's annual revenue.

IV. REGULATORY FRAMEWORK

A. Federal and State Government Health Programs

19. The Federal and State governments, through its Medicaid, Medicare and TRICARE programs, are among the principal purchasers of Defendant's products.

20. Medicare is a federal government health program primarily benefitting the elderly created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"). Medicare began paying for over-the-counter drugs or for most self-administered prescription drugs after the Medicare Prescription Drug Improvement and Modernization Act of 2003 was fully implemented.

21. TRICARE is the healthcare system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and its dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits.

22. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for about 8 million Federal employees, retirees, and its dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan.

23. FEHBP plans are managed by the Office of Personnel Management.

B. The False Claims Act

24. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States. The FCA was again strengthened by additional amendments in 2009 and 2010. The 2009 amendments expanded defendant liability, strengthened retaliation protections, and made it easier for federal, state, and local governments to prosecute FCA actions. The 2010 amendments clarified the definition of who is an "original source" of a FCA disclosure.

25. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1), (2), (7). The FCA empowers private persons who have information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The FCA complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

26. Knowingly paying kickbacks or undisclosed price discounts to physicians to induce them to utilize reimbursable medical devices or equipment, and promoting off-label uses of such devices by a person who seeks reimbursement from a Federal Government health program for the drug, or who causes another to do so, while certifying compliance (or while causing another to so certify) with the Medicare Fraud & Abuse/Anti-Kickback Statute, the Medicaid Rebate Statute, and

the Food, Drug and Cosmetics Act, or billing the Government as if in compliance with these laws, violates the FCA.

C. FDA Regulation of Drug Marketing and Advertising

27. The FDA regulates drugs and medical devices based on the "intended uses" for such products. A manufacturer that wishes to market any new drug must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a), 360b(a).

28. "Off-label" refers to the marketing of a drug for a use that goes beyond the FDA's scrutiny and approval, *i.e.*, for purposes not approved by the FDA.

29. Each state Medicaid program has the power to exclude any drug from coverage if the prescription is not issued for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B). A "medically accepted indication" includes only those indications approved by the FDA and certain "off-label" uses that are "supported by one or more citations included, or approved for inclusion, in any of the compendia" listed in the statute. 42 U.S.C. § 1396r-8(k)(6). Many States further restrict drugs by prior-approval processes that aim to restrict off-label uses.

30. Pursuant to the FDCA, 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates, among other things, the content of direct-to-physician product promotion and labeling information used by medical companies in promoting and selling FDA-approved drugs. In particular, sales representatives who engage in personal interactions with providers may not promote drugs for use outside the FDA approved label and indications.

31. Any failure by a drug manufacturer to fairly and accurately represent the approved uses, safety and other required information about a prescription drug is considered misbranding and is, as a matter of law, a false and fraudulent statement. 21 U.S.C. §§ 331(a)-(b), 352(a), (f), (n).

32. The United States and the Plaintiff States and Cities would not have issued reimbursements for off-label sales had they known the truth about Defendant's illegal marketing scheme. Every reimbursement sought from Medicaid, Medicare, TRICARE and other government health care programs for such purchases or prescriptions as a result of Defendant's aggressive and illegal off-label marketing constitutes a false claim under the FCA.

D. The Medicare Fraud & Abuse/Anti-Kickback Statute

33. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also covers Medicaid, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by a fine of up to $25,000 and imprisonment for up to 5 years.

34. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals, or from receiving remuneration that takes into account the volume or value of any referrals or business generated. 42 C.F.R. § 1001.952(f). Remuneration paid to providers is an illegal kickback when it is paid to induce or reward the drug prescriptions written by physicians. Kickbacks are harmful to public policy because they increase the expenditures paid by government-funded health benefit programs by inducing medically unnecessary use of prescription drugs and excessive reimbursements. Such kickbacks also reduce a patient's healthcare choices as unscrupulous or unknowing physicians steer its patients to various drug products based on the physician's own financial interests rather than the patient's medical needs.

35. The Medicare Anti-Kickback Statute provides eight statutory exceptions from its statutory prohibitions, and certain regulatory "safe harbors" have been promulgated to exclude certain types of conduct from the reach of the statute. 42 U.S.C. § 1320a-7(b)(3). None of the available statutory exceptions or regulatory safe harbors protect Defendant's conduct in this case.

36. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of any individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party violated the Medicare Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended the Act to include administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. 42 U.S.C. § 1320a-7a(a)(7).

37. As detailed below, Defendant's marketing repeatedly violated provisions of the Anti-Kickback Statute and the FCA because Defendant's improper kickbacks and incentives induced physicians to prescribe Defendant's drug when they otherwise would not have and many of those prescriptions were paid for by Medicaid and other Government funded health insurance programs.

38. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a *per se* prohibition against kickbacks.

39. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-

funded medical services, including services provided under Medicare, Medicaid, and/or TRICARE/CHAMPUS programs.

V. DEFENDANT'S MARKETING SCHEMES PROHIBITED BY THE FCA

A. Background

40. H.P. Acthar® Gel (repository corticotrophin injection) ("Acthar") is derived from a bovine or porcine source of the adrenocorticotropic hormone (ACTH), which stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and other androgenic substances. Acthar stimulates the body to produce its own steroidal substances.

41. Acthar is currently approved in the U.S. for the treatment of acute exacerbations of multiple sclerosis in adults, and as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. It is also indicated to induce a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus, as well as indicated for the treatment of several other diseases and disorders.

42. FDA originally approved Acthar for various uses in 1952 (without the rigorous approval process required today) for a wide range of applications; however, it was eventually eclipsed by the development of synthetic steroids.

43. In fact, synthetic steroids have been demonstrated to be equally effective as Acthar in most applications; they also are simpler to produce than Acthar, readily available, and inexpensive. Accordingly, usage of Acthar dropped significantly throughout the medical community.

44. For example, by the 1990s, use of Acthar to treat acute exacerbations of multiple sclerosis (MS) was vanishing because of the ready availability of synthetic steroids. The few clinical studies that existed showed that Acthar was no more effective than intravenous (IV) steroids in the treatment of acute exacerbations of MS.

45. The one condition for which Acthar continued to be used was a rare pediatric disorder called infantile spasms. Guidelines published by the American Academy of Neurology and Child Neurology Society supported use of Acthar as the standard of care. However, until 2010, there was no FDA approved indication for Acthar's use to treat infantile spasms.

46. Questcor purchased the rights to Acthar in 2001. The company invested in upgrading the manufacturing process and worked with the FDA to receive orphan drug status for the product in 2003. Nevertheless, Questcor continued to lose money on Acthar for the next three years. Questcor sought approval from the FDA for use of Acthar to treat infantile spasms, but its application was twice rejected for lack of adequate data on efficacy and safety.

47. Facing years more work with the FDA to gain approval for an infantile spasm indication, Questcor dramatically changed its business strategy. On August 27, 2007, it increased the price of a single vial from approximately $2,000 to $23,000. One course of treatment for infantile spasm suddenly cost as much as $80,000 to $100,000. By the fourth quarter of 2007, Questcor was making a profit.

48. In 2008, the company began to invest heavily in marketing for its treatment of acute exacerbations of MS. However, the idea of treating MS with Acthar had many inherent difficulties.

49. The treatment of choice for years to treat such flare-ups -- IV steroids -- was inexpensive, readily available, and easily covered by insurers, allowing patients to initiate treatment for its MS exacerbations almost immediately. By contrast, a full regimen of Acthar for the same condition demanded 3 to 6 vials of Acthar at $23,000 to $29,000 per vial, required preauthorization from most insurers, and had to be shipped from a specialty pharmacy in a process that generally took one to three weeks before a patient could get started with treatment.

50. Nevertheless, Questcor's aggressive marketing in the MS medical community showed results. In early 2009, Questcor heralded two straight quarters of more than 50% growth in new MS prescriptions as well as growth in refills. As a result, the company announced that it was doubling its sales force in the MS arena. At that time, Questcor estimated that 20% of net sales of Acthar were for treatment of MS.

51. By mid-2009, Questcor was reporting yet more expanded sales for treatment of MS, moving the condition up to one-third of total sales.

52. In October, 2010, the FDA at last approved Acthar for treatment of infantile spasms, but, by then, Questcor was having such success with its marketing strategy for MS that MS remained its primary focus. Questcor worked with the FDA to "modernize" the drug label, an effort that included dropping several indications for which Questcor "did not expect to generate any meaningful net sales in the next several years." The company was careful to retain the MS indication as well as others that it believed could net significant sales with a concentrated marketing effort.

53. By the end of 2010, Questcor had expanded its MS-focused sales force four times, doubling it from 38 to 77 people in the fourth quarter of 2010 alone. It now stands at 107.

54. Questcor hired Relator Clark in September 2010, during the time the company was dramatically expanding its sales force to market Acthar to treat acute exacerbations of MS.

55. MS-related sales leapt to account for 77% of new prescriptions. In 2011, sales for MS continued to skyrocket, increasing 254% over 2010. The company more than doubled its sales again in 2012, reaching net sales of $509 million compared with $218 million in 2011.

56. Meanwhile, Questcor did not initiate a comprehensive compliance program until October 2011 and did not roll out compliance information to its field sales staff until early 2012.

57. Questcor first articulated its internal compliance requirements to its sales staff at a program in February 2012.

B. Improper Promotion of the 5-Day Dosing Regimen

58. Acthar's approved dosing for acute MS exacerbations calls for "daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks . . .. It may be necessary to taper the dose." The full dosing information also states, "Dosage should be individualized according to the medical condition of each patient. Frequency and dose of the drug should be determined by considering the severity of the disease and the initial response of the patient."

59. The approved dosing regimen would require as many as three to six vials or more of Acthar (each vial contains five 80-unit doses), for a total cost of $75,000 to $140,000.

60. By comparison, treatment with solumedrol (methylprednisolone), the steroidal treatment that is the standard of care for a MS flare-up, costs approximately $2,000 or less.

61. The Acthar regimen also requires patients to self-administer injections daily for several weeks, which compares unfavorably with the three days of infusions (undertaken in a hospital outpatient visit) necessary for the solumedrol treatment.

62. Questcor faced the difficult problem of convincing doctors to prescribe a drug that was not proven to be superior to steroids, at an exorbitant cost and lengthier treatment when administered in accordance with the label.

63. To address this problem, Questcor marketed the drug by focusing on appropriate "patient types" for Acthar, among whom were people who had had adverse reactions or tolerability problems with IV steroids.

64. Questcor trained its sales representatives to encourage healthcare providers to search for patients that had had any adverse event or inadequate response to steroids, and solicit these patients as appropriate candidates for Acthar treatment. Notably, however, the drug insert for

Acthar makes clear that "[c]ommon adverse reactions for H.P. Acthar Gel are similar to those of corticosteroids," because adverse responses to the two drugs both relate to their steroidogenic effects.

65. Nevertheless, Questcor represented Acthar as an alternative for people who had adverse responses to IV steroids and marketing materials promoted the idea that it could be tolerated better.

66. The clear import of Questcor's written marketing materials – which sales representatives were trained to repeat in person – was that Acthar was better tolerated than steroids.

67. Various Questcor marketing materials for Acthar made improper or false claims:

a. A glossy handout in which Questcor profiles a patient who allegedly experienced "steroid psychosis" on IV solumedrol, but tolerated Acthar well without side effects.

b. A brochure where the patient profiled reportedly experienced "irritability, insomnia, and anxiety" on solumedrol, but reported "no significant side effects" with Acthar.

c. Another sales piece quotes a patient as saying that steroids made her "miserable," but Acthar did not

68. Notwithstanding Questcor's glossy marketing brochures, clinical evidence actually shows that adverse responses to Acthar are generally the same as those for IV steroids; there is no evidence supporting the claim that Acthar is better tolerated when given in the recommended dosage.

69. Questcor maintained its fiction of superior tolerability by promoting the "Brod protocol" -- a simpler and shorter five-day dosing regimen that only requires one vial of the drug. This dosing protocol solved two important problems for Questcor: (1) patients receive only one-third of the recommended dosage, so they report fewer side effects, lending credibility to

Questcor's unsupported claim of superior tolerability for Acthar; and (2) the $24,000 to $29,000 price tag of a single vial seems practically affordable when compared with the cost of administering the drug per the label's instructions.

70. In one of Relator Clark's first training sessions, a conference call in September 2010, one of Questcor's sales trainers, Jessica Wettstein, outlined how sales representatives should promote the 5-day dosing of the Brod Protocol.

71. Sales representatives were told that five days of Acthar is equal to 3 days of solumedrol.

72. However, there are no peer-reviewed studies showing that a five-day dosing regimen of Acthar is equally effective to a three-day treatment with solumedrol. To the contrary, studies comparing the two drugs find similar efficacy between a three-day dose of solumedrol and the approved, two-to-three-week dose of Acthar.

73. Relator Clark, as well as other Questcor sales representatives, were also instructed to "prefill" insurance forms with patient information, as well as other data, for the healthcare provider. Representatives would leave these pre-filled order forms with medical staff for easy access when an appropriate candidate for Acthar might call.

74. The "Brod protocol" was based on the ideas of Staley A. Brod, M.D., a Professor of Neurology at the University of Texas. Dr. Brod first promoted the 5-day dosing regimen, notwithstanding the lack of any peer-reviewed studies demonstrating its efficacy.

75. Also, Dr. Brod was among the numerous doctors and nurses paid by Questcor to travel and promote Acthar to their colleagues. He and others conveyed to audiences of neurologists, nurses and patients that they rarely used anything other than the five-day dosing

schedule. Dr. Brod and other paid Questcor speakers did not, however, cite supporting data for the short-term regimen other than anecdotal stories from patients.

76. However, it was not just doctors who promoted the five-day dosage. For example, in a May 2011 email, Questcor Northwest Regional Manager John Russell told his entire sales force that "more than 60% of MS use with Acthar requires only one vial of the drug." One vial is a five-day dose.

77. Literature prepared by Questcor's Medical Science Liaisons (MSL) addressing the five-day dosing regimen states clearly that the five-day dose is an off-label use of the drug, and offers only one tidbit of data.

78. Addressing the 5-day dose, the MSL letter cites to a study sponsored by Questcor and published in 2011, which occurred after Questcor began promoting the five-day regimen. That study was an open-label clinical trial involving 21 subjects that sought subjective patient assessments for efficacy of a five-day dose of Acthar administered intramuscularly or subcutaneously. The study did not compare the 5-day dose to a placebo, or to the approved three-day dose of solumedrol, or to the two-to-three week regimen of Acthar. Instead, it simply recorded patient's subjective responses to questions about their symptoms and experience with the drug on the five-day regimen.

79. Molly Nickerson, a Questcor Medical Science Liaison ("MSL"), made clear to Relator Clark in a June 4, 2012 email that the five-day dosing schedule was off-label. She told him in a phone call of the same date that it could only be discussed with doctors by a MSL after an unsolicited medical information request form was submitted by a doctor.

80. Yet that is not what happened. Questcor sales representatives routinely told doctors, nurses, and other medical staff that they should prescribe the five-day dosage and even prepared prescription forms for them with the five-day dosing regimen already written in.

81. Acthar is not available at pharmacies. Instead, Questcor distributes it exclusively through its "Acthar Support & Access Program" (ASAP) system.

82. Prescribing doctors or their staff fill out an ASAP form indicating the patient, the insurer, the reason for the prescription, the dosage, the route of administration (intramuscular or subcutaneous), and the types and quantity of needles to go with the prescription. They fax the form to Questcor's ASAP program, where Questcor staff follow up to seek insurance approval, co-pay support for the patient, and, once approved, arrange delivery directly to the patient. In this way, Questcor maintains tight control over communications with insurers and advocates to ensure insurance coverage.

83. Questcor trained sales representatives to pre-populate the ASAP forms with prescription information and give the forms to nurses who would identify patients that could be candidates for Acthar. If a patient contacted the doctor with an exacerbation of their MS, the nurses would have the forms ready to go.

84. Questcor sales trainers like Jessica Wettstein coached sales staff throughout her region to write in the 5-day dosing regimen, along with needle types and the administration method, on the pre-printed forms before the individual patient even appeared. Sales representatives wrote in a flat, 5-day dosing schedule that made no distinction among individual patients, the severity of their disease or their symptoms.

85. Questcor's compensation plan for the sales force provided commissions for these off-label prescriptions of Acthar.

86. Questcor sales representatives were paid by the "referral" – meaning, each prescription written – regardless of the number of vials of Acthar sold. While the company's official policy was not to pay for off-label uses of the drug, it routinely paid sales commissions for prescriptions for the five-day dosing.

87. Indeed, the vast majority of prescriptions being written were for the off-label, five-day dosing regimen, a fact of which Questcor management was well aware. Because the company handled every order through the ASAP program, they knew exactly what each doctor prescribed.

88. By mid-2011, Questcor began to notice that the average prescription size had been trending down over the period of time that they had increased their sales force. Questcor management presented this information to the sales representatives in the form of what they called a "Super Size Kicker Program."

89. Questcor published documentation showing that while the average new prescription in 2008 was for 1.6 vials, by late 2011 it was down to 1.2 vials. Without speculating on a reason why the average prescription size had dropped by 25% over only three years – at the same time that the company quadrupled the size of its sales force – they pushed the sales reps to try to "supersize" the average prescription.

90. Materials explaining the "Super Size Kicker Program" noted that the company stood to gain $7.6 million in added revenue if the average prescription size grew.

91. Similarly, in the fourth quester of 2011, Questcor offered an extra bonus to sales representatives in any region that increased the average vials per prescription.

C. Improper Promotion of Acthar for Treatment as "Pulse Therapy"

92. Questcor also marketed Acthar for "pulse" therapy for multiple sclerosis, which is an off-label use of the drug for chronic treatment to control symptoms of the disease, rather than limiting its use to an acute exacerbation.

93. "Pulse therapy" is the administration of supra-pharmacologic doses of drugs in an intermittent manner to enhance the therapeutic effects and reduce the side effects.

94. Acthar is not approved for pulse therapy, and there is no peer-reviewed scientific evidence that it is effective in treatment of the disease.

95. Nevertheless, Questcor sales staff discussed the possibilities of pulse therapy with MS physicians as part of their physician marketing program.

96. A November 2010 email from Regional Director John Russell to National Sales Director Doug Harmon reports that his region's "MS Physician Marketing" efforts include:

> [S]everal new consultant meetings with thought leaders we now have access to . . .. Concentration on MOA, 4 Patient types, and exploring Pulse ACTH use as a first line therapy and as a long term potential therapy . . .. Most all KOL [key opinion leader] MSologists that I have talked to think that there will be a potential place for pulse ACTH in the $7-8 Billion Disease Modifying Market. They are seeking more efficacy . . . that is safe!

D. Questcor Provides Kickbacks

a. Questcor Pays Speakers To Promote Acthar

97. Questcor maintained an active list of more than fifty doctors and nurses who had speaker agreements with Questcor to travel around the country to speak to healthcare providers about Acthar.

98. For most presentations, Questcor paid its speakers $2,000 per event, even if the "event" was only a visit with a physician in the break room of his or her office with a passing mention of the drug. Records show that it was not unusual for a program to have only one attendee.

99. The company did not place requirements on the content of the presentations, which, in Relator Clark's experience, often lacked slides or data, as well as required disclaimers advising that the speaker was paid by Questcor.

100. Speakers routinely promoted the five-day dosing regimen at these events, in front of Questcor sales force, as well as regional managers and other marketing staff, notwithstanding FDA restrictions against such off-label promotion at paid speaker events.

101. Questcor encouraged this conduct, even touting in advertisements for the speaker programs that Dr. Brod headlined that he would "describe an optimal dosing and administration schedule."

102. Questcor trained the speakers and created and approved the slides to be used in the presentations. The Questcor-created slide deck included information about a five-day dosing regimen.

103. When Relator Clark started working for Questcor in 2010, there was no limit to the number of events at which a single doctor could speak over the course of a year. Some of the favored speakers such as Dr. Brod or Andrew H. Woo, M.D. (Santa Monica, CA), earned hundreds

of thousands of dollars in a single year from Questcor. Dr. Woo sought to do as many programs in a day as possible. In one email string arranging a series of programs, he pushed to do four in a day rather than three and signed the emails, "Woopert Murdoch" and "Wootillionaire."

104. Questcor also paid for all of the speaker's travel expenses, in addition to the $2,000 per event.

105. Speakers generally required at least two to three presentations per day as a condition of agreeing to travel.

106. As a result, events for which a speaker would be paid $2,000 might include a simple coffee or office visit with a single practitioner.

107. Also, speakers used the program as a way to receive free travel. For example, Relator Clark has emails arranging a visit to Oregon by Brian Steingo, M.D. (a neurologist from Pompano Beach, Florida), who wanted to travel to Seattle, Washington.

108. Dr. Steingo contacted Questcor and asked about flying to the Northwest as a speaker to promote Acthar. Questcor told its sales representatives to set up talks for Dr. Steingo to justify the travel, with one even noting that they should set him up with several events so that he would see the "value" of traveling all the way to the Pacific Northwest.

109. Questcor management undertook no monitoring of the events either for attendance or for content. Sales staff sometimes fabricated the number of people present at meetings. When sales staff asked about cancelling events at which they did not have enough RSVPs, they were told by Questcor management to hold them anyway.

110. The message to the sales staff and the paid promoters was that the important thing was the opportunity for the promoting doctors to "earn" their speaker fees.

111. At some of the events, MSL Molly Nickerson spoke to medical providers together with the marketing staff, in violation of FDA regulations.

112. Besides permitting Questcor sales representatives to arrange these events for doctors and nurse practitioners to improperly promote Acthar, Questcor management also encouraged Questcor sales representatives to invite doctors and purse practitioners who were heavy prescribers of Acthar to become paid speakers.

113. Sales representatives suggested to targeted doctors that they could join the speakers' list and travel, at Questcor's expense, to promote the drug at $2,000 per "event."

114. In order to be able to speak with knowledge and experience about Acthar, these doctors had a strong incentive to use it in their practices. This opportunity to earn easy cash was intended to induce providers to prescribe more Acthar.

b. Questcor Provides Gifts and Inducements to Medical Staff

115. In addition to direct payments to doctors to prescribe and promote Acthar, Questcor also gave gifts and inducements to staff including RNs, medical assistants, billing staff, office managers and receptionists. These gifts helped sales representatives gain access to prescribers and rewarded medical staff for identifying Acthar candidates, working through the prior authorizations, pushing insurers to approve coverage, and encouraging patients to wait, sometimes up to three weeks, while ASAP secured insurance approval.

116. Sales representatives were encouraged to bring coffees or other beverages to the office staff on a regular basis. For example, Regional Manager (Mountain Region) Sheri Trutwin sponsored a contest for sales reps to take coffees to at least two offices daily, offering cash bonuses to the sales staff who achieved the most "coffee drops."

117. Questcor sales representatives were encouraged and coached to buy gift cards at Starbucks, Cheesecake factory, and other food-related outlets and give them out to office staff.

118. Relator Clark's Regional Manager John Russell encouraged his staff to reward nursing staffs with anything that could be purchased at a restaurant or any kind of food item, such as Godiva chocolates, fruit gift baskets, bakery items, etc.

119. Questcor sales representatives were also encouraged and instructed to put the purchases on their expense report as simply a food purchase as if it was their personal consumption, and the expenses were routinely approved.

120. These inducements worked. For example, Relator Clark worked with the office manager in one doctor's office to arrange a lunch with the doctor, and he had some trouble scheduling. When she agreed to let him change the date, she remarked, "OK, BUT I'M TOTALLY KEEPING THE STARBUCKS CARD! :) Thanks Scott!!"

121. These tactics were encouraged and disseminated from the highest levels at Questcor. For example, Questcor managers encouraged sales staff to come up with "success stories," and training staff then emailed them out to colleagues nationwide. Time and again the sales reps mentioned free meals, coffees and goodies as key strategies.

122. One "success story" circulated by one of the sales representatives to his colleagues is typical:

> [W]orked through lunches, Golf fund raisers, wine committee, coffee drops, candy drops, charm, wit and good looks to develop some rapport with nurses. I suppose this is where I say I create a 'sense of need' with Dr. Calkwood to write Acthar for his patients (just being honest) – he then threw me a bone . . ..

123. Another "success story" is described as follows:

> [T]hrough persistence, weekly visits with snacks, finding out key bits of info from the staff (fav foods/drinks), I was able to gain full access to the office. . . . lots of communication, follow through and pampering the office with various snack drops.

124. The same sales specialist continues by explaining to management that he "finally convinced office to go out to dinner/ HH [happy hour] after they used Acthar a couple of times." *Id*.

125. Questcor sponsored contests among sales representatives that pushed them to use incentives to get access and referrals for Acthar. Contests encouraged sales representatives to take healthcare providers out for "interactions" – in other words, Questcor-paid entertainment -- outside the office.

126. Another, similar effort was the "outside the office influence contest" in the summer of 2011, intended to curry favor with key people in medical offices, especially through sponsoring happy hours. Medical discussions were optional; these events were instead meant to develop a relationship with key office personnel who could be asked later for assistance in identifying candidates for Acthar or working through the authorization process. Questcor offered cash prizes to the sales representatives who achieved the highest number of "interactions" outside the office, meaning they were taken out outside of normal business hours.

127. Budgets that Questcor authorized for representatives to spend on "field promotion expenses," i.e., meals or drinks with medical providers, ballooned over the time that Relator Clark was employed, reflecting the primacy of these kinds of interactions in Questcor's marketing efforts.

128. The first budget Relator Clark received, for fourth quarter 2010, authorized $2,500 per sales representative per month to spend entertaining health care providers. By 2011, Questcor budgeted nearly eight times that much -- $19,000 per month per representative -- for the same purpose.

129. Northwest Regional Manager John Russell made clear to his staff when he circulated the budgets: "Message to me and you is that you can go out there with confidence and

spend $ that makes sense to get the business." Questcor's National Sales Director, Ed Hardin, also chimed in: "We still have plenty of monies to invest in lunches, dinners, etc. to help us drive business in Q1 so let's make good use of these funds."

130. A few weeks later, Regional Manager Russell passed out a budget tracker to his staff and reminded them that, "We can definitely say that the company allows us to go make things happen and we don't have a bunch of $ spending restrictions."

E. <u>Other Misconduct</u>

a. Questcor Coaches Healthcare Providers On How to Ensure Reimbursement for Illegal Uses of Acthar

131. Regional Manager Trutwin instructed Relator Clark, as well as other sales representatives, to coach healthcare providers on how to fill out prescription forms so that off-label uses of Acthar would be covered by insurance or Medicare.

132. Upon information and belief, other regional managers around the country instructed their sales representatives to do the same thing.

133. In the Fall of 2011, Regional Manager Trutwin explained to Relator Clark how a physician could get Acthar approved for pulse therapy. She stated that Dr. William Schaeffer of Denver was having success with pulse therapy for his MS patients, and that if the physician used the term "active inflammation" as the diagnosis, then the reimbursement team would not red flag the prescription as off-label. They would work to get the insurer to cover it. MS, by definition, is a form of chronic, "active inflammation" – making the term sufficiently ambiguous that insurers might understand it to mean an acute flare but it could also apply to use for chronic disease management.

134. Again, on February 16, 2012, Relator Clark asked about how Acthar could be covered for pulse therapy and again Regional Manager Trutwin told him to ask the doctor if the patient was having "active inflammation," and then have the nurse put that on the ASAP form.

135. She also suggested having the nurse note "no refills" on the form, so that Relator Clark could get credit each time a new vial was ordered for the same long-term treatment.

136. Questcor coached healthcare professionals not only on how to get Acthar approved by insurers for off-label uses, but they even coached medical staff on questions to ask patients to set them up as candidates for Acthar rather than steroids.

137. Managers provided forms that healthcare providers could fill out to "stimulate discussion" about relapse therapy, whether IV steroids had been successful, and what kinds of side effects patients had on them. Questcor also created assessment forms to document the specific information that an insurer would want to see in the chart to justify use of Acthar, as well as a list of leading questions to ask patients to show that they had experienced a variety of possible side effects in their last steroid treatment. Documentation that the patient had "tolerability issues" would help to justify an Acthar prescription.

138. Questcor also "counseled customers" on how to write a letter of medical necessity to an insurer.

139. Eventually they developed a sample letter of medical necessity for sales representatives to use in "coach[ing] our customers" through the ASAP process and appealing adverse insurance decisions. The letters walked the healthcare staff through the elements that the letter should include in order to substantiate a supposed need for Acthar over steroids, such as IV steroid tolerability issues.

b. Questcor Improperly Promotes A Co-pay Assistance Program

140. Questcor funds a co-pay assistance plan through the Chronic Disease Fund, a 501(c)(3) nonprofit charitable organization established by pharmaceutical companies to pay co-pays and provide other financial assistance to patients so that patients do not absorb the cost of using an expensive drug over a less expensive one.

141. Questcor's donations – totaling more than $80 million to date -- are earmarked for the coverage of acute exacerbations of MS, treated with Acthar.

142. The Chronic Disease Fund pays the cost of all deductibles and co-pays applicable to use of Acthar, and specifically provides assistance to Medicare beneficiaries, including Medicare Part D enrollees.

143. By paying the full amount of a Medicare patient's co-pay with a single prescription of Acthar, the program effectively covers the "donut hole" gap in coverage under Medicare for all prescription drugs throughout the coverage year. It is an enormous benefit to patients that is not available if the healthcare provider prescribed IV steroids for the treatment of an acute exacerbation of MS.

144. The Department of Health and Human Services Office of Inspector General (OIG) has concluded that the Chronic Disease Fund's payment of co-pays to Medicare beneficiaries "could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present."

145. Although OIG has stated that the Chronic Disease Foundation's management of the co-pay assistance program did not violate the anti-kickback statute if it operated within restrictions against inducing referrals, Questcor used the program as a direct means of inducing providers to prescribe Acthar to their Medicare patients.

146. Questcor trained its sales representatives to tell doctors and nurses that copay assistance is automatically offered to anyone having a co-pay of $200 or more, and there was no upper limit on the amount that could be covered.

147. Questcor's sales representatives, upon instruction from Questcor management, promoted the fact that Questcor had funded its own separate arena within the Chronic Disease Fund that would only be used to assist patients having an acute MS exacerbation – in other words, it would only assist those receiving Acthar.

148. Questcor management instructed its sales representatives to make sure doctors understood that, "Questcor established an Acute Exacerbations of Multiple Sclerosis 'bucket.' As a result, Acthar patients needing copay assistance will not be using funds provided by [other] manufacturers." Patients would be approved within ten minutes on the phone. Relator Clark reports that sales representatives used language similar to the following when discussing Acthar with physicians, "Doctor, when you prescribe Acthar for a Medicare patient, we will provide copay assistance for that patient and they will pay nothing out of pocket! If the patient uses steroids, and has Medicare, often their copay will be $200-300 for their treatment. Please convey this to the patients considering steroids."

149. For example, sales representative Allison Polich emailed her colleagues with a description of how the co-pay assistance program works for Medicare beneficiaries. She noted that "one of my large offices has been very skeptical regarding our coverage of Acthar for Medicare patients. . . . they wanted to know why Questcor was able to provide this benefit." She explained -- "Questcor has funded 2 buckets: 1. Private bucket for commercial payers, 2. Public bucket for government payers (INCLUDING Medicare)."

150. In other words, she directly linked Questcor's funding of the Chronic Disease Fund to specific allocations of payments for commercial or government-funded payments for Acthar.

151. Ms. Polich also promoted to the medical office that qualified Medicare patients receive 100% copay assistance in the range of $2500-$4500 -- an amount sufficient to cover the donut hole for all prescriptions in an entire year. She boasted, as a selling point to doctors: "*A Medicare patient will NEVER put down a credit card as the CDF foundation will work directly with the specialty pharmacy to cover the copay.*"

152. Circulating her description of Questcor's program to her colleagues, Questcor managers reiterated that Medicare patients "paid ZERO out of pocket!!!!!!!" because of Questcor's funding of co-payment assistance. Sales representatives in the field touted this "benefit" to patients – for whom it was money in their pockets not just for the Acthar prescriptions but for all other prescriptions throughout the year – and to doctors who wanted to help their Medicare patients.

153. Questcor used the copay assistance program as a direct marketing tool, providing generous payments to patients for using Acthar that they would not receive by using IV steroids for their MS flare-ups

F. Questcor Retaliates Against Relator Clark and Terminates Him

154. Relator Scott Clark started with Questcor on September 16, 2010 as an Acthar Specialist.

155. Relator Clark and his colleagues promoting Acthar were paid a commission for each commercially shipped referral of Acthar, so long as the salesperson had reported at least one sales call on the prescriber prior to the referral. Commissions changed over time but were in the range of $1,000 to $5,000 per referral.

156. As described more fully above, Relator Clark had several discussion with his superior, Regional Manager Trutwin, in the Spring of 2012 regarding the marketing of Acthar for

"pulse therapy" and Questcor's suggestion that sales representatives suggest that providers use the designation of "active inflammation" in order to ensure reimbursement.

157. On or about April 5, 2012, Relator Clark contacted Mike Mulroy, Questcor's Senior Vice President, Chief Financial Officer, General Counsel and Corporate Secretary. Relator Clark told CFO Mulroy his concerns about illegal promotion by Regional Manager Trutwin and others of off-label uses of Acthar, resulting in false claims to Medicare and other insurers.

158. On or about April 9, Vice President for Compliance Raymond Furey called Relator Clark and asked him for further details about his concerns related to illegal promotion of off-label uses of Acthar. Relator Clark provided further details.

159. Relator Clark heard nothing back from his reports to Vice President for Compliance Furey or CFO Mulroy. On information and belief, Questcor took no corrective action

160. On or about April 16, 2012, Regional Manager Trutwin called Relator Clark and asked him directly if the compliance office had called him. She told him that someone had called compliance and reported that she was asking her staff to sell off-label. She pressured him to deny that she had ever done that.

161. On or about May 28, 2012, Relator Clark emailed Vice President for Compliance Furey and CFO Mulroy. He reiterated his concerns and told them that he felt that Regional Manager Trutwin had retaliated against him since he reported her compliance violations.

162. The following week, CFO Mulroy called Relator Clark and asked him to fly to San Francisco for a meeting.

163. On June 6, Relator Clark attended a regional meeting in Colorado and had further discussions with Vice President for Compliance Furey. Clark identified several additional areas where Questcor had violated pharmaceutical and regulatory rules, including the anti-kickback

statute. These illegal practices potentially resulted in fraudulent claims for coverage of Acthar to Medicare and other insurers.

164. Among other things, Relator Clark reported to Vice President Furey that regional and national managers instructed sales representatives to use gift cards, gifts of food and drink, and other gifts and services to induce and reward health care professionals for prescriptions. Relator Clark also reported that doctors on the speakers' bureau received high fees for minimal presentations with very few attendees, multiple times in a single day.

165. Vice President for Compliance Furey responded that because these things occurred before Questcor formally instituted its compliance education, he did not intend to pursue it.

166. Relator Clark met with CFO Mulroy and Vice President for Compliance Furey in San Francisco on June 15, 2012. They discussed the concerns that Relator Clark had raised about widespread promotion of off-label uses of Acthar and improper kickbacks to medical staff and doctors. Relator Clark also brought up the five-day dosing schedule, explaining that the company was promoting a dosage that was not only off-label, but also had no reliable data to support that it was effective and safe.

167. CFO Mulroy and Vice President for Compliance Furey said they would get back to him. Relator Clark followed up with an email outlining his concerns on June 18, 2012.

168. On June 20, 2012, Vice President Furey called Relator Clark. He advised Relator Clark that he should not "get sideways" with the company over the compliance issues.

169. On or about June 28, Relator Clark emailed CFO Mulroy and Vice President Furey again. He directly asked for guidance as to whether the sales force was authorized to promote Acthar for "active inflammation" and also whether they could promote the five-day dosing schedule. He indicated that he wanted to stay within the FDA approved guidelines for marketing.

170. Within an hour of Relator Clark's email, he received a phone call from Chief Operating Officer Steve Cartt asking him to come to the Hayward, California home office for another meeting.

171. The following day, June 29, 2012, Relator Clark met with COO Steve Cartt. Relator Clark again began to talk about the kickbacks and off-label promotion of Acthar, but COO Cartt did not engage with him about those issues. Instead, COO Cartt said repeatedly that Relator Clark seemed unhappy working at Questcor and questioned his ability to be an effective sales person. COO Cartt put him on immediate administrative leave and shut off all of his access to company networks and email.

172. Relator Clark remained on administrative leave, and then unpaid leave, for several months until Questcor terminated him on October 8, 2012

COUNT 1
False Claims Act - Presentation of False Claims
31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A), as amended in 2009

173. The allegations of the preceding paragraphs are realleged as if fully set forth below.

174. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information which supported claims to CMS and federal Programs, with actual knowledge of the falsity of the information that supported these claims, causes, and continues to cause, the use of false or fraudulent materials or information to support claims paid by the government.

175. Through the acts described above and otherwise, Defendant and its agents and employees knowingly presented or caused to be presented to the United States Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

176. The United States of America, unaware of the falsity of the claims and statements made by Defendant, and in reliance on the accuracy of these claims and statements, paid and is continuing to pay or reimburse claims for Acthar for patients enrolled in federally-funded medical care programs.

177. As a direct result of Defendant's actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

COUNT 2
False Claims Act - Making or Using False Records or Statements to Cause Claim to be Paid
31 U.S.C. § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B), as amended in 2009

178. The allegations of the preceding paragraphs are realleged as if fully set forth below.

179. Through the acts described above and otherwise, Defendant and its agents and employees knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2), and, as amended, 31 U.S.C. § 3729(a)(1)(B), in order to get false or fraudulent claims paid and approved by the United States Government.

180. The United States of America, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid and is continuing to pay or reimburse claims for Acthar for patients enrolled in federally-funded medical care programs.

181. As a direct result of Defendant's actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

COUNT 3
False Claims Act – Conspiracy
31 U.S.C. § 3729(a)(3), 31 U.S.C. § 3729(a)(1)(C) as amended in 2009

182. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

183. Through the acts described above and otherwise, Defendant entered into a conspiracy or conspiracies to defraud the United States by getting false and fraudulent claims allowed or paid in violation of 31 U.S.C. § 3729(a)(3), and as amended 31 U.S.C. § 3729(a)(1)(C). Defendant also conspired to omit disclosing or to actively conceal facts, which, if known, would have reduced Government obligations to it or resulted in repayments from it to Government programs.

184. Defendant, its agents, and its employees have taken substantial steps in furtherance of those conspiracies, *inter alia*, by preparing false records, by submitting claims for reimbursement to the Government for payment or approval, and by directing its agents and personnel not to disclose and/or to conceal its fraudulent practices.

185. The United States, unaware of Defendant's conspiracy or the falsity of the records, statements and claims made by Defendant, its agents and employees, and as a result thereof, has paid and continues to pay millions of dollars that it would not otherwise have paid. Furthermore, because of the false records, statements, claims, and omissions by Defendant and its agents and employees, the United States has not recovered federal funds from Defendant that otherwise would have been recovered.

COUNT 4
False Claims Act - Making or Using False Records or Statements to Conceal, Avoid and Decrease Obligation to Repay Money
31 U.S.C. § 3729(a)(7), 31 U.S.C. § 3729(a)(1)(G) (as amended)

186. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

187. Through the acts described above and otherwise, in violation of 31 U.S.C. § 3729(a)(7), and, as amended, 31 U.S.C. § 3729(a)(1)(G), Defendant and its agents and employees knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, and decrease Defendant's obligation to repay money to the United States Government that Defendant improperly or fraudulently received. Defendant also failed to disclose material facts that would have resulted in substantial repayments to the United States Government.

188. As a direct result of Defendant's actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

189. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, Defendant knowingly made, used, or caused to be made or used, false or fraudulent records or statements, to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States of America and the *Qui Tam* States in violation of 31 U.S.C. §3729(a)(7).

190. As a direct result of Defendant's actions as set forth in the Complaint, the United States of America, and the *Qui Tam* States, have been, and may continue to be, severely damaged.

COUNT 5
California False Claims Act
Cal. Gov't Code § 12651 *et seq*.

191. The allegations of the preceding paragraphs are realleged as if fully set forth below.

192. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651 *et seq.*

193. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the California Medicaid Program (*i.e.*, Medi-Cal) false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

194. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

195. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 6
Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-4-304 *et seq*.

196. The allegations of the preceding paragraphs are realleged as if fully set forth below.

197. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act. Colo. Rev. Stat. § 25.5-4-304 *et seq.*

198. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the

Colorado Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for, or procedures utilizing, Acthar and used false or fraudulent records to accomplish this purpose.

199. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

200. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 7
Connecticut False Claims Act
Conn. Gen. Stat. § 17b-301a *et seq.*

201. The allegations of the preceding paragraphs are realleged as if fully set forth below.

202. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301 *et seq.*

203. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to an officer or employee of the state and the Connecticut Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

204. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

205. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 8
Delaware False Claims Act
Del. Code Ann. tit. 6, § 1201 *et seq.*

206. The allegations of the preceding paragraphs are realleged as if fully set forth below.

207. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit. 6, § 1201 *et seq.*

208. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

209. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

210. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 9
Florida False Claims Act
Fla. Stat. Ann. § 68.081 *et seq*.

211. The allegations of the preceding paragraphs are realleged as if fully set forth below.

212. This is a claim for treble damages and civil penalties under the Florida False Claims Act. Fla. Stat. Ann. § 68.081 *et seq.*

213. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Florida

Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

214. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

215. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 10
Georgia False Medicaid Claims Act
Ga. Code Ann. § 49-4-168 *et seq.*

216. The allegations of the preceding paragraphs are realleged as if fully set forth below.

217. This is a claim for treble damages and civil penalties under the False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

218. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Georgia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

219. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

220. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 11
Hawaii False Claims Act
Haw. Rev. Stat. § 661-22 *et seq*.

221. The allegations of the preceding paragraphs are realleged as if fully set forth below.

222. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-22 *et seq.*

223. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

224. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

225. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 12
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. 175/1 *et seq*.

226. The allegations of the preceding paragraphs are realleged as if fully set forth below.

227. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act. 740 Ill. Comp. Stat. 175/1 *et seq.*

228. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Illinois

Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

229. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

230. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 13
Indiana False Claims and Whistleblower Protection
Burns Ind. Code Ann. § 5-11-5.5-1 *et seq.*

231. The allegations of the preceding paragraphs are realleged as if fully set forth below.

232. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Law. Burns Ind. Code Ann. § 5-11-5.5-1 *et seq*.

233. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Indiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

234. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

235. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 14
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. Ann. § 46:437.1 *et seq.*

236. The allegations of the preceding paragraphs are realleged as if fully set forth below.

237. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law. La. Rev. Stat. Ann. § 46:439.1 *et seq*.

238. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and knowingly used false or fraudulent records to accomplish this purpose.

239. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

240. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 15
Maryland False Health Claims Act
Md. Code Ann., Health-Gen. §2-601 *et seq.*

241. The allegations of the preceding paragraphs are realleged as if fully set forth below.

242. This is a claim for treble damages and civil penalties under the Maryland False Claims Act, Md. Code Ann., Health-Gen. §2-601 *et seq*.

243. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the

Maryland Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

244. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

245. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 16
Massachusetts False Claims Act
Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

246. The allegations of the preceding paragraphs are realleged as if fully set forth below.

247. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

248. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

249. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

250. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 17
Michigan Medicaid False Claim Act
Mich. Comp. Laws §400.601 *et seq*.

251. The allegations of the preceding paragraphs are realleged as if fully set forth below.

252. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act. MCL § 400.601 *et seq*.

253. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Michigan Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

254. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

255. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 18
Minnesota False Claims Act
Minn. Stat. § 15C.01 *et seq.*

256. The allegations of the preceding paragraphs are realleged as if fully set forth below.

257. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act. Minn. Stat. § 15C.01 *et seq.*

258. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

259. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

260. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 19
Montana False Claims Act
Mont. Code Ann. §17-8-401 *et seq.*

261. The allegations of the preceding paragraphs are realleged as if fully set forth below.

262. This is a claim for treble damages and civil penalties under the Montana False Claims Act. Mont. Code Ann. § 17-8-401 *et seq*.

263. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Montana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

264. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

265. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 20
Nevada False Claims Act
Nev. Rev. Stat. § 357.010 *et seq.*

266. The allegations of the preceding paragraphs are realleged as if fully set forth below.

267. This is a claim for treble damages and civil penalties under the Nevada False Claims Act. Nev. Rev. Stat. § 357.010 *et seq.*

268. The allegations of the preceding paragraphs are realleged as if fully set forth below. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Nevada Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

269. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

270. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 21
New Hampshire Medicaid Fraud and False Claims Law
N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

271. The allegations of the preceding paragraphs are realleged as if fully set forth below.

272. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law. N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

273. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

274. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

275. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 22
New Jersey False Claims Act
N.J. Stat. § 2A:32C-1 *et seq.*

276. The allegations of the preceding paragraphs are realleged as if fully set forth below. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act. N.J. Stat. § 2A:32C-1 *et seq.*

277. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

278. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

279. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 23
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-1 *et seq.*

280. The allegations of the preceding paragraphs are realleged as if fully set forth below.

281. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act. N.M. Stat. Ann. § 27-14-1 *et seq.*

282. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

283. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

284. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 24
New York False Claims Act
N.Y. State Fin. Law § 187 *et seq.*

285. The allegations of the preceding paragraphs are realleged as if fully set forth below.

286. This is a claim for treble damages and civil penalties under the New York False Claims Act. N.Y State Fin. Law § 187 *et seq.*

287. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New York Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records material to a false or fraudulent claim to accomplish this purpose.

288. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

289. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 25
North Carolina False Claims Act
N.C. Gen. Stat. § 1-605 *et seq*.

290. The allegations of the preceding paragraphs are realleged as if fully set forth below.

291. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Stat. § 1-605 *et seq*.

292. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

293. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

294. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 26
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63 § 5053 *et seq*.

295. The allegations of the preceding paragraphs are realleged as if fully set below.

296. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053 *et seq.*

297. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the

Oklahoma Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

298. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

299. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 27
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 *et seq.*

300. The allegations of the preceding paragraphs are realleged as if fully set forth below.

301. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act. R.I. Gen. Laws § 9-1.1-1 *et seq.*

302. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

303. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

304. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 28
Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq.*
Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

305. The allegations of the preceding paragraphs are realleged as if fully set forth below.

306. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and the Tennessee False Claims Act. Tenn. Code Ann. § 71-5-181 *et seq.*

307. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Tennessee Medicaid Program (i.e. TennCare) false or fraudulent claims for the improper payment or approval of prescriptions for Acthar described above and used false or fraudulent records to accomplish this purpose.

308. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

309. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 29
Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

310. The allegations of the preceding paragraphs are realleged as if fully set forth below.

311. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act. Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

312. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly made a claim to the Texas Medicaid Program for a product that has been adulterated, debased, or mislabeled, or that is otherwise inappropriate, and caused to be presented to the Texas Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

313. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

314. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 30
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.1 *et seq.*

315. The allegations of the preceding paragraphs are realleged as if fully set forth below.

316. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act. Va. Code Ann. §8.01-216.1 *et seq.*

317. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Virginia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

318. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

319. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 31
Washington Medicaid Fraud False Claims Act
Wash. Rev. Code Ann. § 48.80.010 *et seq.*

320. The allegations of the preceding paragraphs are realleged as if fully set forth below.

321. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act Wash. Rev. Code Ann. § 48.80.010 *et seq*.

322. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Washington Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

323. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

324. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 32
Wisconsin False Claims Act
Wis. Stat. § 20.931 *et seq.*

325. The allegations of the preceding paragraphs are realleged as if fully set forth below.

326. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act. Wis. Stat. § 20.931 *et seq*.

327. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

328. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

329. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 33
District of Columbia False Claims Act
D.C. Code § 2-308.14 *et seq.*

330. The allegations of the preceding paragraphs are realleged as if fully set forth below.

331. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act. D.C. Code § 2-308.03 *et seq*.

332. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose, and conspired with each other to effectuate this plan.

333. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

334. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 34V
The City of Chicago False Claims Act
Chicago Municipal Code, § 1-22-010 *et seq.*

335. The allegations of the preceding paragraphs are realleged as if fully set forth below.

336. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act. Chicago Municipal Code § 1-22-010 *et seq.*

337. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Chicago Department of Public Health false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

338. The City of Chicago Department of Public Health, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

339. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged in a substantial amount.

COUNT 35
New York City False Claims Act
New York City Adm. Code, § 7-801 *et seq.*

340. The allegations of the preceding paragraphs are realleged as if fully set forth below.

341. This is a claim for treble damages and civil penalties under the New York False Claims Act, New York Adm. Code, § 7-801.

342. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to New York City false or fraudulent claims for the improper payment or approval of prescriptions for Acthar and used false or fraudulent records to accomplish this purpose.

343. The New York City Health and Hospitals Corporation, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

344. By reason of these payments, the New York City Health and Hospitals Corporation has been damaged, and continues to be damaged in a significant amount.

COUNT 36
Iowa False Claims Act
Iowa Code Ann. § 685.1 *et seq*.

345. The allegations of the preceding paragraphs are realleged as if fully set forth below.

346. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. § 685.1 *et seq.*

347. Defendant, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Iowa.

348. By virtue of the kickback scheme described above, Defendant knowingly caused to be presented to the Iowa Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Novartis Drugs.

349. The Iowa Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

350. By reason of these payments, the Iowa Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT 37
Retaliation in Violation of 31 USC 3730(h)

351. The allegations of the preceding paragraphs are realleged as if fully set forth below.

352. Defendant Questcor harassed, threatened, discharged, and otherwise discriminated against Scott Clark in the terms and conditions of his employment because of his efforts to stop false claims from being made to the government through mislabeling, improper promotion of off-label uses of Acthar, unlawful kickbacks, and other acts described above.

353. Because of Defendant's unlawful retaliation, Scott Clark has suffered damages including lost salary, commission, and benefits and other economic losses in an amount that is continuing to accrue and will be determined at the time of trial.

354. Because of Defendant's unlawful retaliation, Scott Clark has suffered emotional distress including but not limited to anxiety, sleeplessness, humiliation, depression, and loss of enjoyment of life. He is entitled to compensation for these damages in an amount to be determined by the jury at trial.

355. Because of Defendant's unlawful retaliation, Scott Clark has incurred attorney fees and costs and other expenses in an amount to be determined at time of trial.

COUNT 38
Unlawful Retaliation for Whistleblowing in Violation of Oregon Revised Statute 659A.199

356. The allegations of the preceding paragraphs are realleged as if fully set forth below.

357. Defendant Questcor harassed, threatened, discharged, and otherwise discriminated against Scott Clark in the terms and conditions of his employment because he reported what he

believed in good faith to be violations of law, rules and regulations to the appropriate compliance authorities.

358. Because of Defendant's unlawful retaliation, Scott Clark has suffered damages including lost salary, commission, and benefits and other economic losses in an amount that is continuing to accrue and will be determined at the time of trial.

359. Because of Defendant's unlawful retaliation, Scott Clark has suffered emotional distress including but not limited to anxiety, sleeplessness, humiliation, depression, and loss of enjoyment of life. He is entitled to compensation for these damages in an amount to be determined by the jury at trial.

360. Because of Defendant's unlawful retaliation, Scott Clark has incurred attorney fees and costs and other expenses in an amount to be determined at time of trial.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendant, ordering that:

a. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*;

b. Defendant pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendant's actions;

c. Relator be awarded the maximum "relators' share" allowed pursuant to 31 U.S. C. § 3730(d) and similar provisions of the state false claims acts;

d. Relator be reinstated with the same seniority status that he would have had but for Defendant's discrimination;

e. Relator be awarded two times his lost compensation with interest thereon, as well as compensation for his emotional distress sustained as a result of Defendant's retaliation;

f. Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S. C. § 3730(d) and similar provisions of the state false claims acts;

g. Relator be awarded all litigation costs, expert fees, and reasonable attorneys' fees incurred as provided pursuant to 31 U.S.C. § 3730(h) and other applicable law;

h. Defendant be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

i. Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and

j. The United States, the Individual States, and Relators recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Respectfully submitted,

By: _____

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